REMARKS

The Office Action of November 28, 2006, has been received and reviewed.

Claims 1-21 are currently pending and under consideration in the above-referenced application, each standing rejected.

Claims 4, 5, 7, and 12 have been canceled without prejudice or disclaimer.

Reconsideration of the above-referenced application is respectfully requested.

Rejections under 35 U.S.C. § 102(e)

Each of claims 1-6, 8, 9, 11, and 13-21 stands rejected under 35 U.S.C. § 102(e) for reciting subject matter which is allegedly anticipated by the subject matter described in U.S. Patent 5,747,274 to Jackowski (hereinafter "Jackowski").

A claim is anticipated only if each and every element, as set forth in the claim, is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 4 and 5 have been canceled without prejudice or disclaimer. Thus, the rejections of these claims are moot.

As amended and presented herein, independent claim 1 is drawn to a method for performing an assay that includes concurrently evaluating the presence of a plurality of analytes in a sample, which includes concurrently determining rates of reaction of each analyte with a corresponding reactive element. The assayed analytes have known parameters that, in combination, are indicative of an acute metabolic or disease state. Amended independent claim 1 also recites that the act of "determining" continues until a combination of reaction rates for the various analytes provides a reliable indication of an acute metabolic or disease state with which the analytes are associated.

Contrary to the Office's assertion at page 4 of the Office Action of November 28, 2006, amended independent claim 1 does not require that that acts of "applying" and "determining" be effected separately from one another.

Of further note, in its Decision, the Board of Patent Appeals and Interferences (hereinafter "the Board") read Jackowski as disclosing a method that includes the "substantially simultaneous" evaluation of a plurality of analytes. Decision, pages 6-7. The Board also noted that "concurrent" evaluation is different from "substantially simultaneous" evaluation. Decision, page 6.

It is respectfully submitted that the teachings of Jackowski relate to end-point assays, which provide a particular result once a set procedure (*e.g.,* incubation of a sample on a test device for a fixed period of time) is complete. Thus, Jackowski does not expressly or inherently describe a method that includes concurrently determining rates of reaction, as required by amended independent claim 1.

It is further submitted that Jackowski does not expressly or inherently describe a method in which a sample is applied to an assay device that carries a plurality of reactive elements, and that a presence of a plurality of analytes in the sample may be ***concurrently*** evaluated. Instead, Jackowski describes that multiple assays for different analytes may be conducted on a single sample that is obtained at a single point in time. Col. 22, lines 12-14. Thus, the amounts of markers that are *simultaneously present* in the sample may be accurately determined. Col. 22, lines 15-19. The different assays may be performed within a given time frame (*e.g.,* thirty minutes) after the sample is obtained. Col. 22, lines 7-8. As an example, in reference to FIGs. 8-11, Jackowski describes a device in which a sample moves, by capillary action, substantially linearly through three detection zones of a membrane at successive points in time. According to Jackowski, such assays are considered to be effected "simultaneously" even though they are not effected at the same point in time, or concurrently. Col. 22, lines 2-19; *see also* col. 29, lines 50-63, col. 30, lines 18-26; col. 35, lines 60-68. In reality, the configuration and intended function (*i.e.,* application of a sample to a sample well, wicking of the sample through the length of the membrane, and sequential passage of the sample through different detection zones at different points in time) prevent multiple analytes potentially within a sample from being concurrently assayed.

Each of claims 2, 3, 6, 8, 9, 11, and 13-21 is allowable, among other reasons, for depending either directly or indirectly from claim 1, which is allowable.

Claim 8 is also allowable because Jackowski does not expressly or inherently describe that a concurrent determination of the presence of at least one analyte in a sample may be effected by reacting a plurality of analytes in a sample with a corresponding reactive elements that have been arranged in patterns on a waveguide surface.

Withdrawal of the 35 U.S.C. § 102(e) rejections of claims 1-6, 8, 9, 11, and 13-21 is respectfully requested, as is the allowance of each of claims 1-3, 6, 8, 9, 11, and 13-21.

Rejections under 35 U.S.C. § 103(a)

Claims 7 and 10-12 have been rejected under 35 U.S.C. § 103(a) for reciting subject matter that is allegedly unpatentable over the subject matter taught in Jackowski, in view of teachings from U.S. Patent 4,224,304 to Sawai et al. (hereinafter "Sawai").

Claims 7 and 12 have been canceled without prejudice or disclaimer, rendering the rejections of these claims moot.

Claims 10 and 11 are both allowable, among other reasons, for depending indirectly from independent claim 1, which is allowable.

Furthermore, it is respectfully submitted that, without the benefit of hindsight provided by the claims of the above-referenced application, one of ordinary skill in the art wouldn't have been motivated to combine teachings from Jackowski and Sawai in such a way as to render obvious the subject matter recited in amended independent claim 1, from which claims 10 and 11 indirectly depend. In particular, the teachings of Jackowski are limited to conducting multiple end-point assays on the same sample, while the teachings of Sawai are limited to evaluating rates of reaction of a single analyte and its corresponding capture molecule to provide an accurate indication of the amount of that analyte in a sample.

Independent claim 1, as amended and presented herein, recites a method that includes evaluating rates of reaction between a plurality of analytes and their corresponding reactive elements. The assayed analytes have known parameters that, in combination, are indicative of an acute metabolic or disease state. A combination of the evaluated reaction rates provide an indication of a presence or absence of an acute metabolic or disease state.

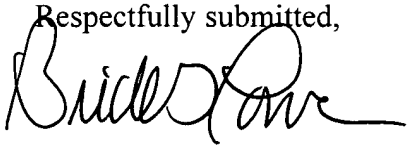
Neither Jackowski nor Sawai provides any teaching or suggestion that would have motivated one of ordinary skill in the art to consider multiple rates of reaction between a plurality of analytes and corresponding reactive elements to diagnose an acute metabolic or disease state. Therefore, teachings from Jackowkski and Sawai do not support a *prima facie* case of obviousness against amended independent claim 1 or any of its dependent claims. As such, the subject matter to which claims 10 and 11 are directed is, under 35 U.S.C. § 103(a), allowable over the subject matter taught in Jackowski and Sawai.

It is respectfully requested that the 35 U.S.C. § 103(a) rejections of claims 7 and 10-12 be withdrawn, and that claims 10 and 11 be allowed.

CONCLUSION

It is respectfully submitted that each of claims 1-3, 6, 8-11, and 13-21 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



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